1636

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE




Application of: ALLEN

Serial No.: 09/900,708

Filed: July 6, 2001

Group Art Unit: 1636

Examiner: Qian, Celine X.

Attorney Docket No.: R-733

For: TRANSGENIC MICE CONTAINING INTESTINAL ALKALINE PHOSPHATASE GENE DISRUPTIONS

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## RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Office Action mailed May 21, 2002, concerning the Examiner's restriction to the claims, Applicants hereby provisionally elect, with traverse, Invention I (claims 1-10 and 17-28), drawn to a targeting construct, a method of making said targeting construct, a cell comprising a disruption in an intestinal alkaline phosphatase gene, an intestinal alkaline phosphatase gene knockout non-human animal and a method of making said non-human animal. This communication confirms the telephonic message left for the examiner on July 19, 2002.

In the restriction, the Examiner asserts that claims 1-34 are drawn to seven distinct subjects, grouped as: Invention I (claims 1-10 and 17-28), drawn to a targeting construct, a method of making said targeting construct, a cell comprising a disruption in an intestinal alkaline phosphatase gene, an intestinal alkaline phosphatase gene knockout non-human animal and a method of making said non-human animal; Invention II (claims 11 and 30), drawn to a method of using a transgenic animal for identifying an agent that modulates intestinal alkaline phosphatase gene expression; Invention III (claims 12, 29, and 31) drawn to a method of using a transgenic animal for identifying an agent that modulates intestinal alkaline phosphatase function; Invention IV (claims 13), drawn to a method of using a cell disrupted of intestinal alkaline phosphatase gene for identifying an agent that modulates intestinal alkaline phosphatase gene expression; Invention V (claims 14, 32, and 33) drawn to a method of using a cell disrupted of intestinal

alkaline phosphatase gene for identifying an agent that modulates intestinal alkaline phosphatase gene function; Invention VI (claims 16 and 34) drawn to an agent that modulates intestinal alkaline phosphatase gene expression; and Invention VII (claims 16 and 34) drawn to an agent that modulates intestinal alkaline phosphatase gene function; with claim 15 generic to groups IV and V. Applicants respectfully request reconsideration and withdrawal of the requirement.

Specifically, the Examiner asserts that the claims of Groups I, VI and VII are patentably distinct because the inventions are drawn to materially distinct compositions. The Applicants disagree with the Examiner's conclusion in that the compositions of Group I are related to the compositions recited in the claims of Groups VI and VII. Therefore, a search and examination on these claims can be made without serious burden to the Examiner.

The Examiner further asserts that the claims of Groups II-V are patentably distinct because the inventions are drawn to methods that require different starting materials, modes of operation, and each method requires different steps. The Applicants disagree with the Examiner's assertion in that the methods of identifying agents that modulate expression and function of intestinal alkaline phosphatase recited in the claims of Groups II-V are related and would not require a separate search or examination that would seriously burden the Examiner.

The Examiner also asserts that the claims of Groups I, II and III are patentably distinct because the invention of Group I can be used in either the method of Group II or Group III. As discussed above, the Applicants disagree with the restriction of the methods of Group II and Group III because the methods of identifying agents that modulate expression and function of intestinal alkaline phosphatase are related. Thus, the Applicants also respectfully assert that the claims of Group I should be examined together with the claims of Groups II and III since these inventions are related as product and process of use.

It also asserted by the Examiner that the claims of Groups II, IV and VI are patentably distinct because the products of Group VI can be made by the method of either Group II or Group IV. As discussed above, the Applicants disagree with the restriction of the methods of Group II and Group IV because these two methods of identifying agents that modulate expression of

intestinal alkaline phosphatase are related. Thus, the Applicants respectfully assert that the claims of Group VI should be examined together with the claims of Groups II and IV since these inventions are related as process of making and product made.

The Examiner further asserts that the claims of Groups III, V and VII are patentably distinct because the products of Group VII can be made by the method of either Group III or Group V. As discussed above, the Applicants disagree with the restriction of the methods of Group III and Group V because these two methods of identifying agents that modulate function of intestinal alkaline phosphatase are related. Thus, the Applicants respectfully assert that the claims of Group VII should be examined together with the claims of Groups III and V since these inventions are related as process of making and product made.

Although Applicants have provisionally elected Group I for purposes of advancing prosecution of the present application, Applicants contend, for the foregoing reasons, that the restriction requirement is improper. Accordingly, Applicants respectfully request reconsideration and withdrawal of the requirement.

Respectfully submitted,

Date: 22 July 2002

[signature] (Reg. No. 47,536)

Jane K. Babin, Reg. No. 47,224

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Enclosures

**CERTIFICATE OF MAILING UNDER 37 CFR 1.8**

I hereby certify that this correspondence and its listed enclosures is being deposited with the United States Postal Service as First Class Mail, postage paid, in an envelope addressed to: Assistant Commissioner for Patents and Trademarks, Washington, D.C. 20231, Box NF Amendment on **July 22, 2002**

Name: **Don Mixon**

Signed: [signature] Date: 7/22/02

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

| APPLICATION NO | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO | CONFIRMATION NO |
|---|---|---|---|---|
| 09/900,308 | 07/06/2001 | [illegible] | [illegible] | |

7590 05/21/2002

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| EXAMINER | |
|---|---|
| QIAN, CELINE X | |
| ART UNIT | PAPER NUMBER |
| | 6 |

DATE MAILED: 05/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.



Response Due 20-June-02

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JUL 30 2002
PATENT & TRADEMARK OFFICE

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/900,708 | ALLEN, KEITH D |
| Examiner | Art Unit |
| Celine Qian | 1636 |

AUG 06 2002
TECH CENTER 1600/2900

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-34* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4)☐ Interview Summary (PTO-413) Paper No(s). _____
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other

## DETAILED ACTION



Claims 1-34 are pending in the application.

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10 and 17-28, drawn to a targeting construct, a method of making said targeting construct, a cell comprising a disruption in a intestinal alkaline phosphate gene, a intestinal alkaline phosphate gene knockout non-human animal and a method of making said non-human animal, classified in class 536, subclass 230.1, class 435, subclass 91.41, class 800, subclass 13 and 21.

II. Claims 11 and 30, drawn to a method of using a transgenic animal for identifying an agent that modulates intestinal alkaline phosphate gene expression, classified in class 800, subclass 3.

III. Claims 12, 29 and 31, drawn to a method of using a transgenic animal for identifying an agent that modulates intestinal alkaline phosphatase function, classified in class 800, subclass 3.

IV. Claim 13, drawn to a method of using a cell disrupted of intestinal alkaline phosphatase gene for identifying an agent that modulates intestinal alkaline phosphatase gene expression, classified in class 435, subclass 320.

V. Claims 14, 32 and 33, drawn to a method of using a cell disrupted of intestinal alkaline phosphatase gene for identifying an agent that modulates intestinal alkaline phosphatase gene function, classified in class 435, subclass 320.

VI. Claims 16 and 34, drawn to an agent that modulates intestinal alkaline phosphate gene expression, classified in class 800, subclass 3.

VII. Claims 16 and 34, drawn to an agent that modulates intestinal alkaline phosphate gene function, classified in class 800, subclass 3.

Claim 15 is generic to groups IV and V and will be examined in so far as it reads on the elected subject matter.

The inventions are distinct, each from the other for the following reasons:

The inventions of Groups I, VI and VII are patentably distinct because the inventions are drawn to materially distinct compositions. The transgenic animal of Group I, the agents that modulates the expression of intestinal alkaline phosphatase of Group VI, and the agents that modulates the function of intestinal alkaline phosphatase of Group VII are chemically, biologically and physically distinct from each other. A search of the subject matter of one group would not be co-extensive with a search of the other group and hence would be burdensome. Each group is capable of supporting a separate patent. Therefore, the inventions of Group I, VI and VII are patentably distinct.

The inventions of Groups II-V are patentably distinct because the inventions are drawn to methods that require different starting material and modes of operation. Each method requires different steps. A search of one method would not be co-extensive with a search of the other methods and would be burdensome. Therefore, the inventions of Groups II-V are patentably distinct.

Inventions I and II, III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the invention of Group I can be used in either in the method of Group II or Group III. Therefore, the inventions of Group I-III are patentably distinct from each other.

Inventions II, IV and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the products of Group VI can be made by the method of either Group II or Group IV. Therefore, the inventions of Groups II, IV and VI are patentably distinct from each other.

Inventions III, V and VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product of Group VII can be made from the method of either Group III or Group V. Therefore, the inventions of Groups III, V and VII are patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. A search of the subject matter of one group would

not be co-extensive with a search of the other group and hence would be burdensome. Each group is capable of supporting a separate patent.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.
May 13, 2002

DAVID GUZO
PRIMARY EXAMINER